



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

DATE: OC

October 15, 1980

SUBJECT:

EPA Registration No. 1022-LRU
PQ-675 WATER RESISTANT PRESERVATIVE: Caswell # # 253

FROM:

Deloris F. Graham

FHB/TSS

I 11/3/80

TO:

Henry Jacoby

Product Manager (21)

Applicant: Chapman Chemical Company

Chapman Chemical Company

P. O. Box 9158 Memphis, TN 38109

Active Ingredient:

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Dermal Irritation studies. These studies were conducted by Cannon Laboratories, Inc., Reading, Pennsylvania. These studies are under Accession numbers: 242801, 242802, 242803, 242804, and 242805. Cite-all method of support is used.

## Recommendations:

- The Acute Oral, Acute Dermal, Eye Irritation and Skin Irritation studies are acceptable to support the conditional registration of this product.
- 2. The Acute Inhalation Study is not acceptable to support the conditional registration of this product. The actual concentration (not the nominal concentration) must be 5 mg/l or data, to show that the concentration attained is the highest possible attainable concentration of the formulation.
- FHB/TSS has no objections to the conditional registration of this product under the Cite-all method based on the data submitted and substantially similar products already registered. However, an acceptable Acute Inhalation Study must be submitted prior to reregistration.

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## Label:

- Based on the data reviewed the appropriate signal word is CAUTION.
- 2. The heading "Precautionary Statements" subheadings "Hazards to Humans and Domestic Animals" and "Environmental Hazards" must precede "Directions for Use."
- 3. Under the heading "Environmental Hazards," the statement "Keep out of lakes, streams or ponds." must be revised to the following statement, "Do not apply directly to lakes, ponds or streams."
- 4. This label must bear the statement "This product contains petroleum distillates." placed in close proximity to ingredient statement.
- 5. For correct labeling procedure and format please see attached copy.

## Review:

1. Acute Oral Toxicity Study: Cannon Laboratories, Inc., April 30, 1980; Lab no. OF-7259, Accession No. 242804.

Procedure: 5M and 5F Sprager-Dawley (207-240g) rats received a 5g/kg dose of the test material. Observations were made at 1, 3 and 6 hours following dosing and daily thereafter for 14 consecutive days. Necropsies were performed on all animals. LD<sub>50</sub> greater than 5g/kg.

Results: No mortalities. Symptoms observed included loose stool, decreased locomotion activity, piloerection, ptosis, oily ventral surface. No gross abnormalities revealed at necropsy.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

 Acute Dermal Toxicity Study: Cannon Laboratories, Inc; April 30, 1980; Lab no. OF-7260; Accession no. 242803.

Procedure: 5M and 5F New Zealand white rabbits (2.59 - 3.23 Kg)
received a 2g/kg dose of the test material at abraded skin sites under occlusive wrap for 24 hours. Observations were made daily for 14 days after the exposure period. Necropsies were performed on all animals.

Results: No mortalities. Animals gained weight. At 24 hours moderate to severe erythema and moderate edema at all sites. At 48 hours eschar formation. During the second week of study eschar cracked and flaked off revealing deeper eschar and rough, scaly alopecia skin. LP0 greater than 2g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

Acute Inhalation Toxicity: Cannon Laboratories, Inc.; May 2, 1980;
Lab no. OF-7261; Accession no. 242805.

<u>Procedure:</u> 5M and 5F Sprague-Dawley rats (228-275g) were exposed to a 5.0mg/l nominal concentration of the test material for 4 hours.

The test was conducted in a 40-liter glass exposure chamber. The sides and the bottom of the chamber for testing and exhaust of the atmosphere. The port in the bottom of the chamber was centered over a 10 cm hole in a wooden platform. A funnel (8.5 cm in diameter) was brought from the underside of the platform through the hole and centered on the port in the bottom of the chamber. Dynamic airflow was maintained within the chamber by connecting the funnel to a vacuum pump for continuous changing of the chamber atmosphere. The screen used as flooring for the animals raised them to a level such that the side ports in the chamber were in the breathing zone of the animals. Samplings for measurements of particle size and concentration of the test substance were made from these side ports. The test substance was placed in syringe and a syringe infusion pump was used to meter the substance into a stainless steel 1/4 J spraying atomizer.

The airflow for this exposure was maintained at 14 l/minute with an Aalborg FMD-34-39 air flow meter. Nominal concentration for the exposure was determined by dividing the amount of the test substance used by the total air volume. Animals were observed at one hour intervals for signs of toxicity. Following exposure animals were observed for 14 days.

Results: Nominal concentration was 5.0mg/l. Atmospheric concentration was 0.757-0.047. Particle size analysis was 1.48-0.27. Chamber temperature was 76°F. Relative humidity was 78%. Chamber oxygen concentration was 20.9%.

Clinical Observations - during the 4 hours exposure, ptosis, lacrimation, red skin about the face. At 4 hours animals were back to normal and remained normal throughout the 14-day observation

period. Majority of animals gained weight. No gross abnormalities at necropsy.

Study Classification: Core Supplementary Data. The actual due to the large dose concentration (not the nominal concentration) must be 5mg/1: Seel and no mortality

4. Eye Irritation Study: Cannon Laboratories, Inc; April 25, 1980;
Lab no. OF-2767; Accession no. 242801.

Procedure: 9 New Zealand white rabbits (2.61 - 3.0 Kg) received 0.1 ml dose of the test substance in one eye of each of the rabbits. The animals were divided into two groups. Group I consisted of 6 rabbits with treated unwashed eyes. Observations were made at 24, 48 and 72 hours as well as 4 and 7 days after dosing.

Results: At 24-hours in Group I, 1/6 animals had corneal opacity (1/6 = 15), no iris irritation, 6/6 conjunctive redness (2/6 = 2, 4/6 = 3) and discharge (1/6 = 1, 4/6 = 2, 1/6 = 3) and 5/6 conjunctive chemosis (2/6 = 1, 3/6 = 2). Corneal opacity had cleared by 72 hours and all other irritations by day 7.

In Group II, at 24 hours, no corneal opacity or iris irritation, but 3/3 animals had conjunctive redness (3/3 = 1) and 1/3 conjunctive discharge (1/3 = 1). All irritation had cleared by 72 hours.

Study Classification: Core Guideline Data.

5. Dermal Irritation Study: Cannon Laboratories, Inc.; May 14, 1980;
Lab no. OF-7263; Accession no. 242802.

Procedure: 6 New Zealand white rabbits (2.61-2.89 Kg) received 0.5 ml dose of the test material at 2 abraded and 2 intact sites per animal under occlusive wrap for 24 hours. Observations were made at 24 and 72 hours as well as 4 through 16 days.

Results: At 24 hours, very slight to well defined erythema and very slight to well defined edema. At 72 hours severe erythema with slight eschar formation and very slight edema. Erythema persisted in some animals through day 15 but had cleared by day 16. Edema had cleared by day 4. Dermal Irritation Index was 3.04.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

Attachment

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